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EXAMINER

PATEL, SHEFALI DILIP

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on November 11, 2009, Applicant amended claims 29, 32, and 36.
2. Applicant added new claim 48.
3. In the non-final rejection of August 11, 2009, Examiner objected to claims 32 and 36 for minor informalities. Applicant amended claims 32 and 36. Objection is withdrawn.
4. Currently, claims 26, 29-33, 35-39, and 48 are under examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 31, 32, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 31, the claim recites the limitation "the frequency". There is insufficient antecedent basis for this limitation in the claim, as "a frequency" has not been previously introduced in the claim or in prior claim 29. *Originally, in the claims of June 17, 2009, there was antecedent basis for the term "the frequency" in claim 29; however, in the claims of November 11, 2009, the term "frequency" has been removed from claim 29.*

In regards to claim 32, the claim recites the limitation "frequency". There is insufficient antecedent basis for this limitation in the claim, as "a frequency" has not been previously

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introduced in the claim or in prior claim 29. *Originally, in the claims of June 17, 2009, there was antecedent basis for the term "frequency" in claim 29; however, in the claims of November 11, 2009, the term "frequency" has been removed from claim 29.*

In regards to claim 36, the claim recites the limitation "the... frequency". There is insufficient antecedent basis for this limitation in the claim, as "a frequency" has not been previously introduced in the claim or in prior claims 29 or 35. *Originally, in the claims of June 17, 2009, there was antecedent basis for the term "the... frequency" in claim 29; however, in the claims of November 11, 2009, the term "frequency" has been removed from claim 29.*

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 26, 29-32, 35, 39, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US 2001/0044592), and further in view of Claude (US 4,982,742).

In regards to claims 26 and 29, Li et al teaches a device (Figure 5, system [200]) for treating tissue, the device comprising:

- a. a pair of electrodes (electrodes [202][204])
- b. a control unit (controller [208]) for passing alternating current to a treatment area via the electrodes [202][204] and for constantly varying the amplitude (paragraph [0058])

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Li et al does not teach a dressing for applying to the treatment area, wherein the electrodes are affixed to a treatment surface of the dressing and the control unit is integrated with the dressing. Claude teaches a device (Figures 1-5, apparatus [10]) for treating tissue, which includes a dressing (bandage layers [12][14]) for applying to a treatment area, electrodes (electrodes [34][44]) that are affixed to a treatment surface of the dressing, and a control unit (circuit strip [26] containing circuitry [28]) that is integrated with the dressing. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the electrodes and control unit, of the device of Li et al, to be integrated with a dressing, as taught by Claude, as the dressing will provide a convenient means for storing the electrodes and control unit in one integral, self-contained package for generating and applying current across a soft tissue wound (column 1, lines 17-23).

In regards to claim 30, in a modified device of Li et al and Claude, Li et al is silent about whether the alternating current is varied between 50 and 500 microamps. Claude only teaches that the current ranges from 100 to 1000 microamps. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current to be varied between 50 and 500 microamps, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (current range) involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 31, in a modified device of Li et al and Claude, Li et al teaches that the frequency of the alternating current is varied between 1 Hz to 1 kHz; however, Li et al is silent about whether the frequency of the alternating current is specifically varied between 10 and 900 Hz. But it would have been obvious to a person having ordinary skill in the art at the

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time the invention was made to modify the frequency of the alternating current to be varied between 10 and 900 hertz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (frequency range) involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 32, in a modified device of Li et al and Claude, Li et al is silent about whether the time period between each variation of amplitude and/or frequency is 0.1 s. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the time period between each variation of amplitude and/or frequency to be 0.1 s, since it has been held that discovering the optimum value of a result effective variable (time period) involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regards to claim 35, in a modified device of Li et al and Claude, Li et al teaches that the control unit [208] comprises electronic circuitry connected to the pair of electrodes [202][204] (Figure 5) (paragraph [0082]); however, Li et al is silent about whether the control unit further comprises a housing and that the housing includes the electronic circuitry for connecting to the pair of electrodes. Claude teaches that the control unit [26][28] comprises a housing (top overlay layer[12]) with electronic circuitry in the housing [28] connected to the pair of electrodes [34][44]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the control unit, of the modified device of Li et al and Claude, with a housing with the electronic circuitry of the control unit in the housing, as taught by Claude, as the housing will cover and provide a protect shield to the control unit (column 3, lines 17-27).

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In regards to claim 39, in a modified device of Li et al and Claude, Li et al does not teach a removable tab including a metallic strip that connects the electrodes [202][204] and only allows current to pass once the tab is removed. Claude teaches that a removable tab (pull away tab [52]) is electro-mechanically connected between a power source [50] and a ground point on the control unit [28]. When the tab [52] is intact, the power source [50] is connected to ground point and energization of the control unit [28] does not occur. Once the tab is removed, the electrical connection between the power source [50] to ground point is broken, and as result, the power source [50] drives the control unit [28] to generate current toward the electrodes (column 3, lines 37-45). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the modified device, of Li et al and Claude, with a removable tab, as taught by Claude, as the removable tab will provide a means for controlling the energization of the control unit to allow for or prevent delivery of current to the electrodes (column 3, lines 37-45). Further, Claude is silent about whether the removable tab [52] is metallic. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the removable tab to include a metallic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also, it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient conductivity, such as a metal, in electrical energy applications.

In regards to claim 48, in a modified device of Li et al and Claude, Li et al teaches that the control unit is also for constantly varying the frequency of the alternating current (paragraph [0058]).

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9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al and Claude, as applied to claim 29 above, and further in view of Tapper (US 2002/0173473).

In regards to claim 33, in a modified device of Li et al and Claude, Li et al is silent about whether the alternating current specifically has a ramp waveform, since Li et al only states that a variety of waveforms can be utilized, such as both symmetric and asymmetric waveforms, including waveforms having square, triangular, sinusoidal, saw-tooth and trapezoidal shapes and the like. Tapper teaches a device for treating tissue (Abstract), wherein alternating current has a ramp waveform (paragraphs [0016][0056]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current, of the modified device of Li et al and Claude, to have a ramp waveform, as taught by Tapper, as the relatively slow rise and decay evident from the leading and trailing edges of the ramp waveform provides the desirable electrical ramping up and down of each half cycle of each alternating current signal in order to minimize shock sensations (paragraph [0056]).

10. Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al and Claude, as applied to claim 35 above, and further in view of Jacobsen et al (US 5,860,957).

In regards to claim 36, in a modified device of Li et al and Claude, Li et al does not teach that the electronic circuitry comprises memory storing at least one program for determining the amplitude, frequency, and waveform of alternating current supplied to the electrodes. Jacobsen et al teaches a device (Figures 1-2) for treating tissue, wherein a control unit (control pad [10]) comprises memory (memory [52]) storing at least one program of drug delivery schedules for the

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device. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the control unit, of the modified device of Li et al and Claude, with a memory, as taught by Jacobsen et al, as the memory will store preprogrammed drug delivery schedules for the device and will maintain a record of all the delivered doses of drug to the patient (column 7, lines 13-31)(column 7, lines 63-67).

In regards to claims 37 and 38, in a modified device of Li et al, Claude, and Jacobsen et al, Li et al does not teach that the control unit comprises an i/o port and a wireless transceiver in order to wirelessly connect an external device to the control unit. Jacobsen teaches a system (Figures 1-2) comprising a control unit (control pad [10]) and a dressing (drug delivery patch [20]), wherein a wireless transceiver (external host interface/wireless link [48]) allows an external device (computer, *not referenced*) to wireless connect to the control unit memory [52] for the transfer of data to and from the external device (column 7, lines 28-41). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the control unit, of the modified device of Li et al, Claude, and Jacobsen et al, with a wireless transceiver interface, as taught by Jacobsen et al, as such will allow an external device (computer) to wirelessly update the program of the memory and modify the treatment regimen of the dressing device based on monitored patient parameters (column 7, lines 28-41).

Response to Arguments

11. Applicant's arguments with respect to claims 26, 29-33, and 35-39 have been considered but are moot in view of the new ground(s) of rejection, based on the amendments made and change in scope of independent claim 29.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

02/03/2010

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767